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Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith are copies of applications for patent term extension of U.S. Patent No. 6,265,536 and U.S. Patent No. 6,107,458. The applications were filed on May 13, 2005 and May 12, 2005, under 35 U.S.C. § 156. It is noted that patent term extension applications for the above two referenced patents were also filed for NDA 21-506.

Furthermore, patent term extension applications for U.S. Patent No. 5,376,634 were filed for NDA No. 21-506 and NDA No. 21-754. FDA has determined the regulatory review period for each NDA and has published the same in the Federal Register on March 20, 2006 (for NDA No. 21-506) and on March 23, 2006 (for NDA No. 21-754).

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Stephen G. Baxter
Oblon, Spivak, McClelland, Maier & Neustadt, PC
1940 Duke Street
Alexandria VA 22314

RE: Mycamine® (micafungin sodium)
FDA Docket No. 2006E-0023